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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,857	08/08/2001	Donogh P. O'Brien	P0378P3C6	3539

9157 7590 06/25/2004

GENENTECH, INC.  
1 DNA WAY  
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
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GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/924,857

Applicant(s)

O'BRIEN ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/1/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application. 18-26
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed. 18-20, 22, 23, 26
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected. 21, 24-25
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### DETAILED ACTION

1. Applicant's amendment, filed 4/1/04, has been entered.  
Claims 1-17 have been canceled.  
Claim 18 has been amended.  
Claims 19-26 have been added.
2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.  
This Action will be in response to applicant's amendment, filed 4/1/04.  
The rejections of record can be found in previous Office Action (Paper No.     ).  
is
3. Given that the term of a patent to 20 years<sup>is</sup> measured from the filing date of the earlier U.S. application for which benefit under 35 USC 120, 121 or 365(c) is claimed (see MPEP 201.11, particularly MPEP 201.11 (G)), applicant is invited to review the claim to priority on the first line of the specification.

Applicant is reminded that the priority date of the instant claims was deemed to be the filing date of the priority application USSN 07/209,665, filed 6/21/88, as the previous priority applications USSNs 06/926,977, filed 11/4/86 and 07/110,255, filed 10/20/87 do not support the claimed limitations of the instant application, encompassing methods of inhibiting coagulation with LACI.

4. The previous rejections under 35 U.S.C. § 102(e) as being anticipated by Broze et al. (U.S. Patent No. 5,106,833) and under 35 U.S.C. § 103(a) as being unpatentable over Broze et al. (U.S. Patent No. 5,106,833) further in view of Broze et al. (PNAS 84: 1886-1890, 1987) AND/OR Broze et al. (Blood 71: 335-343, 1988) have been withdrawn in view of applicant's amended and newly added claims as well as arguments, filed 4/1/04.

It appears that the the prior art does not teach methods of treating patient having an atherosclerotic plaque with LACI.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 21 and 24-25 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.  
The specification as originally filed does not provide support for the invention as now claimed:  
(A) each recitation of "about" in claim 21 and  
(B) the recitation of the order of the first and second bolus in claims 24 and 25.

Applicant's amendment, filed 4/1/04, directs support to certain pages of the instant specification.

The specification as filed does not appear to provide a written description for these limitations.

For example, there does not appear to be sufficient written description for each recitation of "about" in claim 21 with respect to the range of doses (e.g. see pages 16-17, overlapping paragraph of the instant specification).

While pages 16-17 of the instant specification appear to provide for administering the combination of LACI and a thrombolytic agent, the written description of administering each agent in a particular first and second bolus is not readily apparent.

The specification does not provide sufficient landmarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

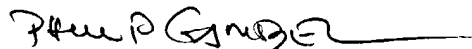
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.

Primary Examiner

Technology Center 1600

June 21, 2004